DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 6, 2015

Abbott Medical Optics, Inc.
Ms. Nooshin Azizi
Senior Regulatory Affairs Specialist
1700 E. St. Andrews Place
Santa Ana, CA 92705

Re: K143434
Trade/Device Name: One Series ULTRA Cartridge, Model 1VIPR30 and the UNFOLDER Platinum 1 Series Cartridge, Model 1MTEC30
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I
Product Code: MSS
Dated: March 26, 2015
Received: March 27, 2015

Dear Ms. Azizi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143434

Device Name
ONE SERIES Ultra Cartridge, Model 1VIPR30
The UNFOLDER Platinum 1 Series Cartridge, Model 1MTEC30

Indications for Use *(Describe)*
Either the DK7786 or DK7791 handpiece is used in combination with the ONE SERIES Ultra Cartridge, Model 1VIPR30 to fold and assist in inserting AMO intraocular lenses that allow use of this injector in the approved IOL labeling, ONLY into the capsular bag.

The Model DK7796 handpiece is used in combination with the Model 1MTEC30 cartridge to fold and assist in inserting AMO intraocular lenses that allow use of this injector in the approved IOL labeling, ONLY into the capsular bag.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

APPLICANT INFORMATION

Abbott Medical Optics Inc. (AMO) is submitting an Abbreviated 510(k) premarket notification for the One Series ULTRA Cartridge, Model 1VIPR30 and the UNFOLDER Platinum 1 Series Cartridge, Model 1MTEC30. This 510(k) Summary is being submitted in accordance with the Medical Device Amendments of 1976, the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92.

Submitter Information:

Abbott Medical Optics Inc.
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Contact Person:

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N. Azizi

Date of 510(k) Summary Preparation: May 4, 2015

Subject Device:

Trade/Proprietary Name:	One Series ULTRA Cartridge, Model 1VPR30 and The UNFOLDER Platinum 1 Series Cartridge, Model 1MTEC30
Common Name:	IOL Cartridge
Classification Name:	Intraocular Lens Guide
Product Code:	MSS
Regulatory Class:	I

SUBSTANTIAL EQUIVALENCE SUMMARY

The One Series ULTRA Cartridge, Model 1VIRP30 and the UNFOLDER Platinum 1 Series Cartridge, Model 1MTEC30, are used in combination with the reusable titanium handpieces by Duckworth & Kent (United Kingdom), Model DK7786 and DK7796 (K081382) to fold and assist in the insertion of AMO Intraocular lenses that allow use of 1VIPR30 and 1MTEC30 in the approved IOL labeling, ONLY into the capsular bag. The cartridges, Model 1VIPR30 and Model 1MTEC30, are single-use devices composed of injection-molded polypropylene. A lubricious coating is applied to the interior surface of the cartridge to facilitate delivery of the IOL into the eye and to prevent IOL damage.

The difference between the new 1VIPR30 and 1MTEC30 Cartridges and their predicate device, Cartridge Model 1VIRP30, which is manufactured by AMO and was cleared by FDA on October 2, 2008 (K081545), is the replacement of the biologically-derived internal coating material with a synthetic coating material. The coating will serve as a lubricating agent to reduce friction between the IOL and the polypropylene cartridge through which the IOL travels during insertion.

DEVICE DESCRIPTION

The One Series ULTRA Cartridge, Model 1VIPR30, remains unchanged with respect to the predicate device that was cleared on October 2, 2008 under 510(k) K081545. The only modification to the 1VIPR30 device in comparison to the predicate device is with the coating material on the inside of the cartridge. The 1MTEC30 Cartridge is a smaller version of the 1VIPR30 and was assessed under a 510(k) Note-To-File. Both the 1VIPR30 and the 1MTEC30 Cartridges are used to fold and assist in the insertion of AMO Intraocular lenses that allow use of this 1VIPR30 and 1MTEC30 in the approved IOL labeling, ONLY into the capsular bag following cataract extraction; the tip of the cartridge has direct contact with the eye. They are both single-use devices composed of injection-molded polypropylene. The coating of the cleared 1VIPR30 Cartridge (predicate device) is biologically-derived material. The new coating will be made of synthetic materials that meets the same functional specifications of the predicate 1VIPR30 Cartridge.

TECHNOLOGICAL CHARTACTERISTICS

No changes have been made to the design, manufacturing process, sterilization method and indication for use of the 1MTEC30 and 1VIPR30 Cartridges when compared to the FDA-cleared 1VIPR30 Cartridge. The change to the IOL cartridge is only to the coating material used on the inside of the device.

INDICATIONS FOR USE

The Indications for Use statement of the One Series ULTRA Cartridge, Model 1VIPR30 and The Platinum 1 Series , Model 1MTEC30 are the following:

Either the DK7786 or DK7791 handpiece is used in combination with the ONE SERIES Ultra Cartridge Model 1VIPR30 to fold and assist in inserting AMO intraocular lenses that allow use of this injector in the approved IOL labeling, ONLY into the capsular bag.

The Model DK7796 handpiece is used in combination with the Model 1MTEC30 cartridge to fold and assist in inserting AMO intraocular lenses that allow use of this injector in the approved IOL labeling, ONLY into the capsular bag.

SUMMARY OF NON- CLINICAL TESTS

Design verification and validation testing was performed on the 1MTEC30 Cartridge to evaluate IOL recovery properties following simulated surgical manipulation (ISO 11979-3:2012) of the TECNIS 1-Piece Soft Acrylic Lens under worst-case conditions.

Design verification was also performed on the 1VIPR30 Cartridge to evaluate IOL recovery properties following simulated surgical manipulation (ISO11979-3:2012) of the TECNIS 1-Piece Soft Acrylic Lens under worst-case conditions.

SUMMARY OF CLINICAL TESTS

No clinical studies were deemed necessary to determine the safety and effectiveness of the One Series Ultra Cartridge, Model 1VIPR30 and the UNFOLDER Platinum 1 Series Cartridge, Model 1MTEC30.

CONCLUSIONS

The design verification and validation studies confirmed that the One Series ULTRA Cartridge, Model 1VIPR30 and The UNFOLDER Platinum 1 Series, Model 1MTEC30 with the new synthetic coating perform to the same specifications as the predicate device.

The data from the non-clinical studies demonstrate that the device is as safe and as effective as the legally marketed predicate device.

The One Series ULTRA Cartridge, Model 1VIPR30 and The UNFOLDER Platinum 1 Series Cartridge, Model 1MTEC30 will be manufactured in compliance with FDA and ISO quality system requirement